



US009408887B2

(12) **United States Patent**
Kleinberg et al.(10) **Patent No.:** **US 9,408,887 B2**
(45) **Date of Patent:** **Aug. 9, 2016**(54) **INTERMITTENT DOSING REGIMEN FOR TREATING BREAST CANCER**(71) Applicants: **David L. Kleinberg**, New York, NY (US); **Mary Helen Barcellos-Hoff**, New York, NY (US)(72) Inventors: **David L. Kleinberg**, New York, NY (US); **Mary Helen Barcellos-Hoff**, New York, NY (US)(73) Assignee: **New York University**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/487,197**(22) Filed: **Sep. 16, 2014**(65) **Prior Publication Data**

US 2015/0099700 A1 Apr. 9, 2015

Related U.S. Application Data

(62) Division of application No. 13/564,873, filed on Aug. 2, 2012, now Pat. No. 8,835,123.

(60) Provisional application No. 61/574,414, filed on Aug. 2, 2011.

(51) **Int. Cl.****A61K 38/12** (2006.01)**A61K 38/31** (2006.01)**G01N 33/574** (2006.01)(52) **U.S. Cl.**CPC **A61K 38/12** (2013.01); **A61K 38/31** (2013.01); **G01N 33/57415** (2013.01); **G01N 2800/50** (2013.01); **G01N 2800/52** (2013.01)(58) **Field of Classification Search**

None

See application file for complete search history.

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Diagnostic and therapeutic methods pertaining to diseases and disorders of the breast, uterus and ovary are encompassed herein. More particularly, diagnostic methods for early detection of progenitor cells of breast, uterine, and ovarian cancers are described herein. The identification of markers for these cancer predisposing progenitor cells, which co-express the progesterone receptor (PR) and p63, provides tools and methods of use thereof that facilitate early detection of increased frequency of PR/p63 double positive (PR/p63+) progenitor cells in asymptomatic patients and thus, early detection of increased cancer risk in such patients and assessment, diagnostic stratification, and evaluation of therapeutic intervention in symptomatic patients. Therapeutic methods are also encompassed herein, which include detection of PR/p63+ progenitor cells in a patient, wherein detection of increased frequency of PR/p63+ progenitor cells provides information on which basis a determination of therapeutic regimen or an assessment of an ongoing therapeutic regimen can be made.